



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 890

[Docket No. FDA-2016-N-2829]

Medical Devices; Physical Medicine Devices; Classification of the Upper Extremity Prosthesis Including a Simultaneously Powered Elbow and/or Shoulder With Greater Than Two Simultaneous Powered Degrees of Freedom and Controlled by Non-Implanted Electrical Components

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Upper Extremity Prosthesis Including a Simultaneously Powered Elbow and/or Shoulder with Greater Than Two Simultaneous Powered Degrees of Freedom and Controlled by Non-Implanted Electrical Components into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components' classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER]. The classification was applicable on May 9, 2014.

FOR FURTHER INFORMATION CONTACT: Michael Hoffmann, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2640, Silver Spring, MD, 20993-0002, 301-796-6476, Michael.Hoffmann@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i), to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1), the person requests a classification under section 513(f)(2) of the FD&C Act. Under the second procedure,

rather than first submitting a premarket notification under section 510(k) and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of “low-moderate risk” or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This classification will be the initial classification of the device. In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on May 18, 2012, classifying the DEKA Arm System into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II.

On June 15, 2012, DEKA Integrated Solutions Corporation submitted a request for classification of the DEKA Arm System under section 513(f)(2) of the FD&C Act. In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for

its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on May 9, 2014, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 890.3450.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for an upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components will need to comply with the special controls named in this final order. The device is assigned the generic name upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components, and it is identified as a prescription device intended for medical purposes, and intended to replace a partially or fully amputated or congenitally absent upper extremity. It uses electronic inputs (other than simple, manually controlled electrical components such as switches) to provide greater than two independent and simultaneously powered degrees of freedom and includes a simultaneously powered elbow and/or shoulder. Prosthetic arm components that are intended to be used as a system with other arm components must include all degrees of freedom of the total upper extremity prosthesis system.

FDA has identified the following risks to health associated specifically with this type of device, as well as the mitigation measures required to mitigate these risks in table 1.

Table 1.--Upper Extremity Prosthesis Including a Simultaneously Powered Elbow and/or Shoulder With Greater Than Two Simultaneous Powered Degrees of Freedom and Controlled by Non-Implanted Electrical Components
Risks and Mitigation Measures

Identified Risk	Mitigation Measures
Unintended Motion	Electronic Input Testing Software Verification, Validation, and Hazards Analysis Wireless Testing Electromagnetic Compatibility (EMC) Testing Non-clinical Performance Testing Water/Particle Ingress Testing Durability Testing Battery Testing Labeling
Adverse Tissue Reaction	Biocompatibility Assessment
Battery Failure	Battery Testing Water/Particle Ingress Testing Labeling
Electromagnetic Incompatibility	EMC testing Labeling
Electrical Safety Issues (e.g., shock)	Electrical Safety Testing Labeling
Gripping Malfunction	Non-clinical Performance Testing Software Verification, Validation, and Hazards Analysis Labeling
High Risk Activities (e.g., driving)	Labeling
Malfunction Due to Environmental Conditions	Non-clinical Performance Testing Battery Testing Water/Particle Ingress Testing Wireless Testing EMC Testing Flammability Testing Labeling
Use Error	Clinical Studies Human Factors Studies Labeling

FDA believes that the special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness.

An upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components is not safe for use except under the supervision of a practitioner licensed by law to direct the use of the device. As such, the device is a prescription device and must satisfy prescription labeling requirements (see 21 CFR 801.109, Prescription devices).

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components they intend to market.

II. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910-0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910-0485.

List of Subjects in 21 CFR Part 890

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 890 is amended as follows:

PART 890 – PHYSICAL MEDICINE DEVICES

1. The authority citation for part 890 is revised to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Add § 890.3450 to subpart D to read as follows:

§ 890.3450 Upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components.

(a) Identification. A upper extremity prosthesis including a simultaneously powered elbow and/or shoulder with greater than two simultaneous powered degrees of freedom and controlled by non-implanted electrical components, is a prescription device intended for medical purposes, and is intended to replace a partially or fully amputated or congenitally absent upper extremity. It uses electronic inputs (other than simple, manually controlled electrical components such as switches) to provide greater than two independent and simultaneously powered degrees of freedom and includes a simultaneously powered elbow and/or shoulder. Prosthetic arm components that are intended to be used as a system with other arm components must include all degrees of freedom of the total upper extremity prosthesis system.

- (b) Classification. Class II (special controls). The special controls for this device are:

(1) Appropriate analysis/testing must validate electronic compatibility, electrical safety, thermal safety, mechanical safety, battery performance and safety, and wireless performance, if applicable.

(2) Appropriate software verification, validation, and hazard analysis must be performed.

(3) Non-clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use. Performance testing must include:

(i) Mechanical bench data, including durability testing, to demonstrate that the device will withstand forces, conditions, and environments encountered during use.

(ii) Simulated use testing to demonstrate performance of arm commands and available safeguard(s) under worst case conditions and after durability testing.

(iii) Verification and validation of force sensors and hand release button, if applicable, are necessary.

(iv) Device functionality in terms of flame retardant materials, liquid/particle ingress prevention, sensor and actuator performance, and motor and brake performance.

(v) The accuracy of the device features and safeguards.

(4) Non-clinical and clinical performance testing must demonstrate the accuracy of device features and safeguards.

(5) Elements of the device that may contact the patient must be demonstrated to be biocompatible.

(6) Documented clinical experience and human factors testing must demonstrate safe and effective use, capture any adverse events observed during clinical use and demonstrate the accuracy of device features and safeguards.

(7) Labeling for the Prosthetist and User Guide must include:

(i) Appropriate instructions, warning, cautions, limitations, and information related to the necessary safeguards of the device, including warning against activities that may put the user at greater risk (e.g., driving).

(ii) Specific instructions and the clinical training needed for the safe use of the device, which includes:

(A) Instructions on assembling the device in all available configurations,
(B) Instructions on fitting the patient,
(C) Instructions and explanations of all available programs and how to program the device,

(D) Instructions and explanation of all controls, input, and outputs,

(E) Instructions on all available modes or states of the device,

(F) Instructions on all safety features of the device, and

(G) Instructions for maintaining the device.

(iii) Information on the patient population for which the device has been demonstrated to be effective.

(iv) A detailed summary of the non-clinical and clinical testing pertinent to use of the device.

Dated: October 11, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-25001 Filed: 10/17/2016 8:45 am; Publication Date: 10/18/2016]